

**CLAIMS**

1. A process for obtaining cryoprecipitable proteins including a virus inactivation step by heat treatment of a freeze-dried form of said proteins, characterized in that it includes, before transforming the proteins into a freeze-dried form, an initial step of addition, to said proteins, of a stabilizing and solubilizing formulation comprising a mixture of arginine, at least one hydrophobic amino acid and trisodium citrate.

2. A process according to Claim 1, characterized in that the formulation is constituted of the said mixture of arginine, at least one hydrophobic amino acid and trisodium citrate.

3. A process according to Claim 1, characterized in that the arginine is present in a concentration of from 25 to 50 g/l.

4. A process according to Claim 3, characterized in that the concentration of arginine is of from 35 to 45 g/l.

5. A process according to Claim 1, characterized in that the trisodium citrate is present in a concentration of from 0.5 to about 12 g/l.

6. A process according to Claim 1, characterized in that the hydrophobic amino acid is leucine, iso-leucine or a mixture thereof.

7. A process according to Claim 6, characterized in that leucine, iso-leucine or mixture thereof are present in a concentration of from 5 to 15 g/l.

8. A process according to Claim 6, characterized in that the concentration of leucine or iso-leucine or mixture thereof is of from 9 to 11 g/l.

9. A process according to Claim 1,

characterized in that glycine and/or lysine are added to the formulation.

10. A process according to Claim 9, characterized in that glycine and lysine are each  
5 present in a concentration of from 1 to 5 g/l.

11. A process according to Claim 9, characterized in that each of these concentrations of glycine and lysine is of from 1.5 to 2.5 g/l.

12. A process according to Claim 1,  
10 characterized in that the freeze-drying is carried out at temperatures between -40°C and -30°C for 48 hours.

13. A process according to Claim 1, characterized in that the heat treatment of virus  
15 inactivation is carried out at temperatures between 80°C and 90°C for 72 hours.

14. A process according to Claim 1, characterized in that it further comprises, prior to addition of the stabilizing and solubilizing  
20 formulation to a liquid composition of cryoprecipitable proteins, at least one additional step of virus inactivation and/or elimination from the said liquid composition by solvent-detergent and/or by nanofiltration on filters of 35 nm.

15. A process according to Claim 1, characterized in that it is applicable to all cryoprecipitable proteins.

16. A process according to Claim 1, characterized in that it is applicable to at least  
30 one of the proteins selected from Factor VIII, von Willebrand Factor, Factor XIII, fibrinogen and fibronectin.

17. A concentrate of at least one cryoprecipitable protein comprising the stabilizing  
35 and solubilizing formulation added to said at least one protein by the process according to Claim 1.

18. A concentrate according to Claim 17

intended to therapeutic use.

19. A concentrate according to Claim 17, consisting of a reconstituted freeze-dried fibrinogen obtained by the process according to claim 13, in  
5 order to present a filterability of about 2 ml/cm<sup>2</sup> on a filter with a porosity of  $0.20 \pm 0.02 \mu\text{m}$ .

20. A stabilizing and solubilizing formulation for the cryoprecipitable proteins intended to be subjected to a freeze-drying and heat  
10 treatment of virus inactivation, characterized in that it includes a mixture of arginine, present at a concentration of from 35 to 45 g/l, at least one hydrophobic amino acid, and trisodium citrate, present at a concentration of from 0.5 to 12 g/l.

15 21. A stabilizing and solubilizing formulation according to Claim 20, characterized in that it is constituted of the said mixture of arginine, at least one hydrophobic amino acid and trisodium citrate.

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